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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,367	03/16/2001	Nobuaki Takahashi	021286/027 8719	6403

7590 05/21/2002
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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/21/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/811,367	Applicant(s) TAKAHASHI ET AL.	
	Examiner " Neon" Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/30/02.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Fax cover sheet</i> . |

DETAILED ACTION

1. Claims 1-61 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6 and 15-28, drawn to a pharmaceutical composition comprising an agent that binds to an MAFA ligand wherein the agent is an anti-MAFA antibody that **increases** NK cell or T cell activity, and a kit comprising said **antibody**, classified in Class 424, subclass 130.1.
 - II. Claims 1-21, drawn to a pharmaceutical composition comprising a soluble human MAFA **polypeptide** that **increases** NK cell or T cell activity, and a kit comprising said polypeptide, classified in Class 435, subclass 185.1.
 - III. Claims 29-38, drawn to a pharmaceutical composition comprising an agent that binds to an MAFA ligand wherein the agent is an anti-MAFA antibody that **inhibits** NK cell or T cell activity, and a kit comprising said **antibody**, classified in Class 424, subclass 130.1.
 - IV. Claims 39-40, and 45-56, drawn to a method for **inhibiting** an NK or T cell expressed cell surface MAFA binding to a ligand on a target cell using an anti-MAFA **antibody**, classified in Class 435, subclass 7.1.
 - V. Claims 39 and 41-56, drawn to a method for **inhibiting** an NK or T cell expressed cell surface MAFA binding to a ligand on a target cell using a soluble human MAFA **polypeptide** comprises a sequence from about amino acid residues 64 to about amino acid residues 189 of SEQ ID NO: 1, classified in Class 435, subclass 7.1
 - VI. Claim 57, drawn to a method of treating a tumor by stimulating the cytotoxic activity of an NK cell or CTL by administering an **antibody**, classified in Class 424, subclass 145.1.
 - VII. Claim 57, drawn to a method of treating a tumor by stimulating the cytotoxic activity of an NK cell or CTL by administering a soluble MAFA **polypeptide** that binds to a MAFA ligand on tumor cell, classified in Class 424, subclass 185.1.
 - VIII. Claims 58-61, drawn to a method for **inhibiting** an activity of an NK cell or a T cell providing a soluble agent that binds to an NK cell or CTL expressed cell surface MAFA wherein the agent is anti-MAFA **antibody** and wherein the activity is to delays or inhibits

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a **graft, or transplant rejection or an allogenic response**, classified in Class 424, subclass 145.1.

- IX. Claims 58-61, drawn to a method for **inhibiting** an activity of an NK cell or a T cell providing a soluble agent that binds to an NK cell or CTL expressed cell surface MAFA wherein the agent is anti-MAFA **antibody** and wherein the activity is to ameliorates an **autoimmune disease**, classified in Class 424, subclass 145.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products such as antibody and polypeptide that increases or inhibits specific NK cell or T cell activity differ with respect to their structure and physiochemical properties such as inhibiting or stimulating cytotoxic activity of NK or T cells. Therefore, they are patentably distinct.

Inventions of Groups IV-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of stimulating or inhibiting NK or T cell cytotoxic activity versus the methods of treating the specific diseases that differ with respect to their etiology differ with respect to the method steps and endpoints. Therefore, they are patentably distinct.

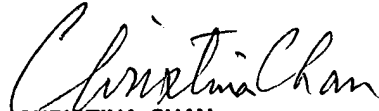
Inventions of Groups (I-III) and Groups (IV-IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide as claimed can be used in materially different process such as making antibody or screening assays. The antibody as claimed can be used in materially different process such as binding or screening assays. Therefore, they are patentably distinct.

3. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

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4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
7. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
May 20, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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